DEC 16 2013

# Section IV: 510k Summary

**Applicant's Identification**

| | |
|---|---|
| Applicant | Grandway Technology (Shenzhen) Limited |
| Address | Block 6 & 7, Zhu Keng Industrial Zone, Ping Shan, Long Gang District, Shenzhen, Guang Dong, People's Republic of China |
| Phone Number | (00852)-2851-6789 |
| Fax Number | (00852)-2851-6278 |
| Contact Person | Mr. Patrick Chow |
| Date of Application | 16th July, 2013 |

**Device's Identification**

| | |
|---|---|
| Trade Name | Digital Automatic Blood Pressure Monitor BPM06 Series<br>**Model No.: MD06x0**<br>*x* --- The first character (0, 1, 3, 5 & 6) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC60601-1 and EN60601-1-2. |
| Common Name | Non-invasive Blood Pressure Measurement System |
| Classification Name | Non-invasive Blood Pressure Measurement System<br>(Class II per 21 CFR 870.1130) |

**Marketed Devices to which Equivalence is Claimed (Predicate Device)**

| | |
|---|---|
| Manufacturer | Grandway Technology (Shenzhen) Limited |
| Device | Digital Automatic Blood Pressure Monitor BPM11 Series<br>(Model No:. MD11xy) |
| 510(k) Number | K120675 |

**Device Description**

Digital Automatic Blood Pressure Monitor BPM06 Series is a non-invasive blood pressure measurement system for use by medical professional or at home. It is designed to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual in each measurement and then display the readings on a digital panel.

The BPM06 Series utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the upper arm of an individual, for blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movement into a digital reading.

**Intended Use (Indication for Use)**

Digital Automatic Blood Pressure Monitor BPM06 Series is for use by medical professional or at home. The BPM06 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual.

**Comparison of Technological Characteristics between New Device and Predicate Devices**

| Comparison between BPM06 Series and predicate device | | | |
|---|---|---|---|
| **Item** | **Predicate Device** | **BPM06 Series** | **Comment** |
| Indication for Use | Digital Automatic Blood Pressure Monitor BPM11 Series is for use by medical professional or at home. The BPM11 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm - 44cm via 3 different size of cuff. 3 different cuff sizes are 17-22cm, 22-32cm and 32-44cm. | Digital Automatic Blood Pressure Monitor BPM06 Series is for use by medical professional or at home. The BPM06 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. | Equivalent |
| Measurement Method | Non-invasive, Oscillometric | Non-invasive, Oscillometric | Identical |
| Irregular Heartbeat Detection (IHB) | Yes | Yes | Identical |
| Patient Population | Age 16 or above | Age 16 or above | Identical |
| Blood Pressure Measurement Range | Cuff Pressure: 0 - 300 mmHg<br>Systolic Pressure: 50 - 250 mmHg<br>Diastolic Pressure: 30 - 200 mmHg | Cuff Pressure: 0 - 300 mmHg<br>Systolic Pressure: 50 - 250 mmHg<br>Diastolic Pressure: 30 - 200 mmHg | Identical |
| Number of User | 2 independent users | 2 independent users | Identical |
| Memory Space | 2 users × 120 memory space | 2 users × 120 memory space | Identical |
| Button (Key) Type | Button Type only | Clock button: Button Type<br>User selection button: Sensor Type | Equivalent, same function |
| Blood Pressure Measurement Accuracy | ± 3 mmHg or 2% of reading | ± 3 mmHg or 2% of reading | Identical |
| Pulse Rate Measurement Range | 30 - 180 beats/min | 30 - 180 beats/min | Identical |
| Pulse Rate Measurement Accuracy | ± 5 % of the reading | ± 5 % of the reading | Identical |
| Display Type | LCD | LCD | Identical |
| Power Source | 4 × 1.5 V AA-batteries; and/or<br>AC adaptor (6V/600mA) | 4 × 1.5 V AA-batteries; and/or<br>AC adaptor (6V/600mA) | Identical |

| Comparison between BPM06 Series and predicate device | | | |
|---|---|---|---|
| **Item** | **Predicate Device** | **BPM06 Series** | **Comment** |
| Pressurization Mode | Automatic Inflation | Automatic Inflation | Identical |
| Deflation Mode | Automatic Exhaust/ Deflation | Automatic Exhaust/ Deflation | Identical |
| Operating Condition | Temperature: 10 - 40 °C<br>Humidity: 30 - 85 % R.H. max<br>Atmospheric Pressure: 700 - 1060 kPa | Temperature: 10 - 40 °C<br>Humidity: 15 - 85 % R.H. max<br>Atmospheric Pressure: 700 - 1060 kPa | Equivalent, improved specification |
| Storage and Transportation Condition | Temperature: -20 - 60 °C<br>Humidity: 10 - 95 % R.H. max<br>Atmospheric Pressure: 700 - 1060 kPa | Temperature: -20 - 60 °C<br>Humidity: 10 - 95 % R.H. max<br>Atmospheric Pressure: 700 - 1060 kPa | Identical |
| Anatomical Sites | 1 - 2 cm above joint | 1 - 2 cm above joint | Identical |
| Material | Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging | Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging | Identical |
| Compatibility with Environment and Other Devices | No influence with environment and other device | No influence with environment and other device | Identical |
| Applicable Standard | ✧ EN 1060-1:1995/A2:2009<br>✧ EN 1060-3:1997/A2:2009<br>✧ IEC 60601-1:2005+ CORR.1(2006)+CORR. 2 (2007)<br>✧ EN 60601-1-2:2007<br>✧ FCC Part 15<br>✧ ISO 10993-5:2009<br>✧ ISO 10993-10:2002 + A1:2006<br>✧ EN 60601-1-4:2007<br>✧ ANSI/AAMI SP-10:2002 | ✧ ISO 10993-5:2009<br>✧ ISO 10993-10:2010<br>✧ EN 1060-1:1997+A2:2009<br>✧ EN 1060-3:1997+A2:2009<br>✧ IEC 60601-1:2012<br>✧ EN 60601-1-2:2007<br>✧ EN 60601-1-4:1996<br>✧ IEC 62304:2006<br>✧ FCC Part 15 Subpart B<br>✧ ISO 81060-2:2009<br>✧ IEC 80601-2-30:2009 | Equivalent, change of FDA recognized standard |

The Digital Automatic Blood Pressure Monitor BPM06 Series is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key components of device are: a pressure sensor, a electric valve and an electronic control module together with an electric pump. The electric pump inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

**Clinical and Non-Clinical Test Summary**

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/IEC 81060-2 as documented in Clinical Test report.

One hundred patients (45 males and 55 females) were recruited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left

upper arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ANSI/AAMI/IEC 81060-2.

Non-Clinical Testing Summary

We have performed bench tests and found that BPM06 Series met all requirement specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- ISO10993-5:2009
- ISO10993-10:2010
- EN1060-1:1995/A1:2002
- EN1060-3:1997+A2:2009
- IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)
- EN60601-1-2:2007
- FCC Part 15 Subpart B
- EN60601-1-4:1996

**Conclusion**

Digital Automatic Blood Pressure Monitor BPM06 Series has the same intended use and similar technological characteristics as the predicate device, BPM11 Series (K120675). Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, the Digital Automatic Blood Pressure Monitor BPM06 Series is substantially equivalent to the predicate device, BPM11 Series (K120675).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Grandway Technology (Shenzhen) Limited
Patrick Chow
Zhu Keng Industrial Zone
Ping Shan, Long Gang District
Shenshen, Guang Dong, 518118 CH

Re: K132240
Trade/Device Name: Digital automatic blood pressure monitor bpm06 series
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 8, 2013
Received: July 30, 2013

Dear Patrick Chow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Additional Information - K132240

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

## Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*

K132240

Device Name

Digital Automatic Blood Pressure Monitor BPM06 Series

Indications for Use *(Describe)*

Digital Automatic Blood Pressure Monitor BPM06 Series is for use by medical professional or at home. The BPM06 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 601 Subpart D) ☒ Over-The-Counter Use (21 CFR 601 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Owen P. Faris -S
Date: 2013.12.16 16:12:50 -05'00'